Ocean State Aquaculture Association

Rhode Island's Aquaculture Trade Association

P.O. Box 2031, Kingston, RI 02881

Dockets Management Branch
(HFA-305) [Docket No. 98P-0504]
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

April 6, 1999

To whom it may concern,

It has been brought to our attention that the FDA is seeking comment on the CSPI petition to establish a zero-tolerance standard for *Vibrio vulnificus* in molluscan shellfish. We feel this would be a costly and dangerous precedent that would irreparably damage to our industry and do little to protect the public health.

V. vulnificus has been associated with only a handful of deaths annually and causes illness in only a select population of susceptible individuals with impaired immune systems. Furthermore, this species of bacterium is a naturally occurring species that is widespread in coastal growing areas. Data also suggest that there is a dose-response relationship, even among susceptible, immune suppressed, individuals, so that limited quantities can be ingested without substantial risk.

It is also apparent that there may be several strains of non-pathogenic *Vibrio vulnificus*. Scientists working in New Hampshire identified *V. vulnificus* in a high percentage of the oysters sampled there (see appended references), and yet, to the best of my knowledge, no one has ever reported an illness or death related to *V. vulnificus* from shellfish harvested in any New England waters.

Until a methodology for differentiating the pathogenic strains from the benign strains of *Vibrio vulnificus* is adopted and widely available, the net result of a zero-tolerance regulation would be to destroy the entire New England shellfish industry. To do so without any indication of an associated risk to public health would be a travesty.

The CSPI petition alludes to the patented Ameripure process of pasteurizing oysters. I have not seen any data to support the claim that this process is 100% effective in eliminating *V. vulnificus*. Present capacity at their processing plant is inadequate to process even a small fraction of the shellfish harvested in US waters. To mandate such processing without adequate justification is pure folly.

Lastly, even if this criteria is established, this would do nothing to stop the illnesses and deaths related to contact with the bacterium through cuts or wounds while swimming or harvesting shellfish in waters where pathogenic *V. Vulnificus* is present.

I would suggest that since *V. vulnificus*-related illnesses have been restricted to the Gulf Coast states, and since illnesses have been seasonal and often associated with improper post-harvest storage procedures that the best course of action until more is known would be to enact seasonal harvest restrictions and impose regulations mandating immediate refrigeration of harvested oysters in the Gulf Coast states.

The Federal Register also seeks comment on the issue of *V. parahemolyticus* in shellfish. Again this is a species with benign and pathogenic strains and there is apparently a dose-response relationship for consumption of the pathogenic strains. Until the techniques for differentiating between the two strains are established and readily available, and until the dose-response relationship is established we feel it would be premature to establish a zero-tolerance standard for this common, naturally-occurring bacterium as well.

Sincerely,

Robert B. Rheault, Ph.D.
President, OSAA

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Pertinent references:

O'Neil, K.R., S.H. Jones and D.J. Grimes. 1990. Incidence of *Vibrio vulnificus* in northern New England water and shellfish. FEMS Microbiol. Lett. 72: 163-168.

O'Neil, K.R., S.H. Jones and D.J. Grimes. 1992. Seasonal incidence of *Vibrio vulnificus* in Great Bay Estuary of New Hampshire and Maine. Appl. Environ. Microbiol. 58: 3257-3262.

Jones, S.H, K.R. O'neil and T.L. Howell. 1991. Differential elimination of indicator bacteria and pathogenic *Vibrio sp.* from Maine oysters in a commercial controlled purification facility. J. Shell Res. 10: 105-112

Jones, S.H. T.L. Howell, K.R. O'Neil and R. Langan. 1995. Strategies for removal of indicator and pathogenic bacteria from commercially harvested shellfish. In: R. Poggiand, J.Y. Le Gall (eds). Shellfish Depuration: Second International Conference on Shellfish Depuration. IFREMER, Brest, France.

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